

**REMARKS**

**Summary of the Office Action**

In the Office Action, claims 1-6 and 11-14 stand rejected under 35 U.S.C. § 102 (b), as being anticipated by newly cited U.S. Patent No. 6,098,617 to *Connell*.

Claims 7 and 8 stand rejected under 35 U.S.C. § 103 (a), as being unpatentable over *Connell* in view of U.S. Patent No. 4,446,869 to *Knodle*.

**Summary of the Response to the Office Action**

Applicant proposes amending claims 1 and 11. Accordingly, claims 1-8 and 11-14 are pending for further consideration (claims 9 and 10 having been withdrawn).

**All Claims are Allowable**

In the Office Action, claims 1-6 and 11-14 stand rejected under 35 U.S.C. § 102 (b), as being anticipated by newly cited U.S. Patent No. 6,098,617 to *Connell*. Claims 7 and 8 stand rejected under 35 U.S.C. § 103 (a), as being unpatentable over *Connell* in view of U.S. Patent No. 4,446,869 to *Knodle*. Applicant traverses these rejections for the following reasons.

With regard to independent claim 1, Applicant respectfully asserts that *Connell* and *Knodle*, whether viewed singly or in combination, do not teach or suggest an apparatus for delivering inhalant to and monitoring exhaled fluid from a patient, the apparatus including at least, “a first cannula having a distal end adapted to be received at a first depth in, for delivering a fluid into, a nostril of the patient; and a second cannula having a distal end adapted to be received at a second depth in, for sampling exhaled fluid from, the nostril, wherein said first and second cannulae being disposed adjacent each other, and a predefined length of said first cannula being disposed substantially separate and independent from a predefined length of said adjacently disposed second cannula, such that upon insertion into the patient’s nostril, said predefined lengths of each cannula being allowed to substantially separately and independently conform to internal contours of the patient’s nostril and air passage, and said predefined lengths of each cannula being substantially separately and independently disposable in contact with the internal contours of the patient’s nostril and air passage,” as recited in independent claim 1, as amended.

Support for these features recited in claim 1 can be found at least in Paragraphs 21 to 29 of the originally filed specification, and in Figs. 1 and 2 of the originally filed drawings. Specifically, as shown in Figs. 1 and 2, the present invention discloses an apparatus 10 for delivering inhalant to and monitoring exhaled fluid from a patient 15. Apparatus 10 includes a first cannula 35 having a distal end 65 adapted to be received at a first depth in, for delivering a fluid into, nostril 17 of the patient, and a second cannula 55 having a distal end 70 adapted to be received at a second depth in, for sampling exhaled fluid from, nostril 17 as well. As shown in Figs. 1 and 2, the first and second cannulae are disposed adjacent each other, and a predefined length of the first cannula is disposed substantially separate and independent from a predefined length of the adjacently disposed second cannula. In this manner, upon insertion into the patient's nostril, the predefined lengths of each cannula are allowed to substantially separately and independently conform to internal contours of the patient's nostril and air passage, and the predefined lengths of each cannula are substantially separately and independently disposable in contact with the internal contours of the patient's nostril and air passage.

*Connell*, as illustrated in Figs. 3-7 and discussed in Col. 5:11-29, discloses an airway 30 including an inhalant gas delivery line 32 and an expired gas sampling line 34 disposed therein. In the embodiment of Fig. 3, lines 32 and 34 include distal ends disposed at first and second distances downstream of airway 30. In an alternative embodiment of the device of *Connell*, as illustrated in Fig. 4 and discussed in Col. 6:1-13, airway 50 is divided into two sections defining side-by-side conduits 56, 58, each respectively including inhalant and exhalant gas lines 60, 62. Moreover, in a further alternative embodiment of the device of *Connell*, as illustrated in Fig. 5 and discussed in Col. 6:14-18, airway 70 is configured as two tubular lumens 72, 74, each respectively including inhalant and exhalant gas lines 78, 79.

In view of the aforementioned teachings, *Connell* clearly discloses a device which includes an airway (i.e. 30, 50 or 70) which functions as a single unit when inserted into the nostril and air passage of a patient, and therefore does not allow the inhalant and exhalant gas lines to separately and independently conform to the internal contours of a patient's nostril and air passage.

On the contrary, as clearly recited in independent claim 1, the present invention provides an apparatus for delivering inhalant to and monitoring exhaled fluid from a patient, for which the

first and second cannulae are disposed adjacent each other, and a predefined length of the first cannula is disposed substantially separate and independent from a predefined length of the adjacently disposed second cannula. In this manner, upon insertion into the patient's nostril, the predefined lengths of each cannula are allowed to substantially separately and independently conform to internal contours of the patient's nostril and air passage, and the predefined lengths of each cannula are substantially separately and independently disposable in contact with the internal contours of the patient's nostril and air passage.

Applicant respectfully asserts that as discussed in the originally filed specification at least in Paragraph 10, to "avoid obscuring, cluttering or obstructing the surgical field, as well as limit patient discomfort, surgeons avoid the use of anesthetizing masks and minimize the size and number of cannulae needed for administering sedation." As further discussed in Paragraphs 10 and 21, this is because conventional cannulae, such as the one disclosed by *Connell*, "typically are received in and/or fully occlude one or both nostrils of a patient, interfering with the surgical field," or "cause discomfort to conscious patients."

It is precisely these drawback in conventional nasal cannulae which led to the invention of the inhalant delivery and exhalant monitoring apparatus of the present invention, which Applicant respectfully asserts was procured by means of extensive testing and experimentation in the field of anesthesiology. Based upon such experimentation, Applicant herein determined the need for an improved apparatus for delivering inhalant to and monitoring exhaled fluid from a patient, and further determined the need for providing the first and second cannula at respective first and second depths in the patient's nostril, whereby a predefined length of the first cannula is disposed substantially separate and independent from a predefined length of the adjacently disposed second cannula, such that, upon insertion into the patient's nostril, the predefined lengths of each cannula are allowed to substantially separately and independently conform to internal contours of the patient's nostril and air passage.

Accordingly, Applicant respectfully asserts that *Connell* clearly does not teach or suggest the aforementioned features recited in independent claim 1.

With regard to the teachings of *Knodle*, Applicant respectfully asserts that *Knodle*, which has been cited as disclosing a moisture trap, does not overcome the aforementioned deficiencies in the teachings of *Connell*.

As pointed out in MPEP § 2131, “[t]o anticipate a claim, the reference must teach every element of the claim.” “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”

*Verdegaal Bros. v. Union Oil Co. Of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

Moreover, as pointed out in M.P.E.P. § 2143.03, “[t]o establish prima facie obviousness of a claimed invention, all the claimed limitations must be taught or suggested by the prior art”. *In re Royka*, 409 F.2d 981, 180 USPQ 580 (CCPA 1974). Therefore, Applicant respectfully asserts that the rejection under 35 U.S.C. § 102 (b) should be withdrawn because *Connell* and *Knodle* do not teach or suggest each feature of independent claim 1.

In view of the above arguments, Applicant respectfully requests the rejection of independent claim 1 under 35 U.S.C. § 102 be withdrawn. Additionally, claims 2-8, which depend from independent claim 1, are allowable at least because their base claim is allowable, as well as for the additional features recited therein.

#### Independent claim 11

With regard to independent claim 11, Applicant respectfully asserts that *Connell* and *Knodle* do not teach or suggest a method of delivering inhalant to and monitoring exhaled fluid from a patient, the method including at least, “inserting to a first depth a distal end of a first cannula in, for delivering a fluid into, a nostril of the patient; and inserting to a second depth a distal end of a second cannula in, for sampling exhaled fluid from, the nostril, wherein said first and second cannulae being disposed adjacent each other, and a predefined length of said first cannula being disposed substantially separate and independent from a predefined length of said adjacently disposed second cannula, such that upon insertion into the patient’s nostril, said predefined lengths of each cannula being allowed to substantially separately and independently conform to internal contours of the patient’s nostril and air passage, and said predefined lengths of each cannula being substantially separately and independently disposable in contact with the internal contours of the patient’s nostril and air passage,” as recited in independent claim 11.

Applicant respectfully asserts that claim 11 is allowable at least for the reasons presented above for the allowance of independent claim 1, and the additional features recited therein. In the interest of avoiding redundant arguments, the arguments presented above for the allowance

of claim 11 are not repeated herein. Additionally, claims 12-14, which depend from independent claim 11, are allowable at least because their base claim is allowable, as well as for the additional features recited therein.

### **CONCLUSION**

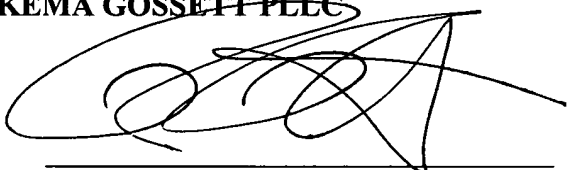
In view of the foregoing, Applicant respectfully requests reconsideration and the timely allowance of the pending claims. Should the Examiner feel that there are any issues outstanding after consideration of the response, the Examiner is invited to contact the Applicant's undersigned representative to expedite prosecution.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 04-2223. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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